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Signed Cerse

Dated 43 OU SOU

16 SEP 1999

Request for grant of a patent
(See the notes on the back of this form. You can also get
an explanatory leaflet from the Patent Office to help
you fill in this form)

The Patent Office

Cardiff Road Newport Gwent NP9 1RH

1. Your reference

DCW/VSW

2. Patent application number (The Patent Office will fill in this part)

9921985.9

16 SEP 1999

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

Britannia Pharmaceuticals Limited 41-51 Brighton Road Redhill Surrey RH1 6YS

5634230001

4. Title of the invention

Medicaments containing Pantothenic Acid

5. Name of your agent (if you have one)

Brookes & Martin

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

High Holborn House 52/54 High Holborn London WC1V 6SE

471001

Patents ADP number (if you know it)

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number (if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application,
give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' 1f:

a) any applicant hamed in part 3 is not an inventor, or

- there is an inventor who is not named as an applicant, or
- c) any named applicant is a corporate body.

See note (d))

yes

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document Continuation sheets of this form 3 Description Claim(s) Abstract Drawing(s) 10. If you are also filing any of the following, state how many against each item. Priority documents Translations of priority documents Statement of inventorship and right to grant of a patent (Patents Form 7/77) Request for preliminary examination and search (Patents Form 9/77) Request for substantive examination (Patents Form 10/77) Any other documents (please specify) 1/We request the grant of a patent on the basis of this application. 11. Signature 12. Name and daytime telephone number of person to contact in the United Kingdom 0171 242 9631 - David C. Woodcraft Warning After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the

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Notes

- a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- b) Write your answers in capital letters using black ink or you may type them.
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This invention relates to medicaments and their use in the alleviation of inflammation and pain in joints.

Pain or loss of movement in joints is a common occurrence, particularly among the elderly or those who have suffered damage to cartilage, bone surfaces or ligaments.

Standard methods of treatment include the administration of corticosteroids by injection into the site of the inflammation. However, relief tends to be temporary and long term use carries a number of contraindications.

Pantothenic acid (sometimes known as vitamin B5) and its salts have been used as a dietary supplement and for treatment of bronchial asthma, hay-fever, sinusitis and neurodermatitis.

It has now been found that pantothenic acid is of value in reducing inflammation when injected into the region of an affected joint.

According to the present invention there is provided use of pantothenic acid or a derivative thereof in the preparation of a medicament for administration by injection into the region of a joint for alleviation of inflammation or pain.

The pantothenic acid may be used in the form of a salt, e.g. the calcium salt. Pantothenic acid is a naturally occurring substance in plant and animal tissue. A particularly rich source is royal jelly obtainable from honey bee colonies. It may be used in its naturally occurring state or as a chemically pure material. Synthetic methods of preparations include those described in US Patent Nos. 2,780,645;

2,845,456 and 2,934,428. The free acid and its salts are optionally active and the dextro-rotatory isomer is preferred.

Conveniently, a medicament is prepared by dissolving the active ingredient, i.e. pantothenic acid or a derivative in a suitable solvent, e.g. water, and injecting the solution into the affected joint. The initial treatment may cause some pain and it may, therefore, be desirable to co-administer a local anaesthetic, e.g. lignocaine, at the same time or shortly before the injection of the pantothenic acid.

Other physiologically active materials may be co-administered, e.g. cysteine or glucosamine.

It may also be desirable to co-administer within the same treatment regime, a surface active phospholipid (SAPL) such as dipalmitoyl-phosphatidyl choline (DPPC) or phosphatidyl glycerol (PG). Preferably, a mixture of DPPC and PG is employed. A preferred protein-free SAPL composition comprising a blend of DPPC and PG is available from Britannia Pharmaceuticals Ltd of Brighton Road, Redhill under the trade mark 'Alec'. SAPL's such as 'Alec' are believed to act as a lubricant in joints, taking over to some extent the function of synovial fluid.

The medicaments of this invention may be used in the treatment of several conditions associated with inflammation or reduced movement of joints. Examples include tennis elbow, housemaid's knee, frozen shoulder, inflamed knee joints and hips and back pain associated with inflammation or restricted movement in the spinal vertebrae.

A typical dose is about 2 mls of an aqueous solution of about 500 mg of the acid salt. The medicament is injected directly into the site of the inflamed joint. A programme of injections is generally desirable in which dosages similar to that indicated above are given at intervals of a few days to about one week. Reduced inflammation and increased freedom of movement is usually noticeable after about a week from the initial injection.

CLAIMS:-

- 1. Use of pantothenic acid or a derivative thereof in the preparation of a medicament for administration by injection into the region of a joint for alleviation of inflammation or pain.
- 2. Use according to claim 1 wherein the derivative is a salt of pantothenic acid.
 - 3. Use according to claim 2 wherein the salt is the calcium salt.
- 4. Use according to any one of the preceding claims wherein the medicament comprises an aqueous solution of pantothenic acid or a derivative thereof.
- 5. Use according to any one of the preceding claims wherein the medicament includes a local anaesthetic.
- 6. Use according to any one of the preceding claims wherein the medicament is co-administered with cysteine or glucosamine.
- 7. Use according to any one of the preceding claims wherein the medicament is co-administered with a surface-active phospholipid (SAPL).
- 8. Use according to claim 7 wherein the SAPL comprises dipalmitoylphosphatidyl choline.
- 9. Use according to claim 7 or 8 wherein the SAPL comprises phosphatidyl glycerol.